IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	)	C.A. No.

COMPLAINT

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring") and Rebiotix Inc. ("Rebiotix") (collectively, "Plaintiffs") bring this action against Defendants Finch Therapeutics Group, Inc., Finch Therapeutics, Inc., and Finch Therapeutics Holdings, LLC (collectively "Defendants") and allege as follows:

THE PARTIES

1. Plaintiff Ferring is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

2. Plaintiff Rebiotix, a Ferring company is a private Delaware corporation having its principal place of business at 2660 Patton Road, Roseville, Minnesota 55113.

3. On information and belief, Defendant Finch Therapeutics Group, Inc. ("FTG") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, Massachusetts 02143. On information and belief, FTG was formed in 2017 as a result of a merger and recapitalization of Finch Therapeutics, Inc.

and Crestovo Holdings LLC. (Ex. 1 at F-8.) On information and belief, Crestovo Holdings LLC was renamed as Finch Therapeutics Holdings LLC. (*Id.*)

4. On information and belief, Defendant Finch Therapeutics, Inc. ("FTI") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, MA 02143. On information and belief, FTI is a wholly-owned subsidiary of Finch Therapeutics Group, LLC.

5. On information and belief, Defendant Finch Therapeutics Holding LLC ("FTH") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Inner Belt Road, Somerville, MA 02143. On information and belief, FTH is a wholly-owned subsidiary of FTG.

NATURE OF THE ACTION

6. This is an action seeking a declaratory judgment that the claims of United States Patents Number 10,675,309 ("the '309 patent") (Ex. 2), United States Patent No. 10,463,702 ("the '702 patent") (Ex. 3), United States Patent Number 10,328,107 ("the '107 patent") (Ex. 4), United States Patent Number 10,064,899 ("the '899 patent") (Ex. 5), United States Patent Number 10,022,406 ("the '406 patent") (Ex. 6), United States Patent Number 9,962,413 ("the '413 patent") (Ex. 7), and United States Patent Number 9,308,226 ("the '226 patent") (Ex. 8) (collectively, the "patents in suit") are invalid or not infringed.

7. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202 and the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. Plaintiffs are seeking United States Food and Drug Administration ("FDA") approval for a new product, designated RBX2660. RBX2660 is an enema preparation containing a liquid suspension of a diverse consortium of fecal microorganisms. To produce the suspension,

fecal samples are collected from pre-screened, healthy donors then blended with a solution consisting of saline and polyethylene glycol ("PEG") to form a slurry. The slurry is then filtered to remove some of the insoluble particulate matter. The suspension is then delivered as a single-dose, ready-to-use enema in a general practitioner's office, or in a clinical or hospital setting. RBX2660 will be indicated for reduce the recurrence of *Clostridium difficile* infection ("CDI") in adults following antibiotic treatment for first or more recurrence of CDI. Recurrence of CDI is also known as "recurrent CDI" ("rCDI").

9. Plaintiffs are seeking a declaratory judgment that the patents in suit are invalid and that RBX2660, once approved by the FDA and sold, will not infringe any valid claims of the patents in suit.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. On information and belief, this Court has personal jurisdiction over FTG. On information and belief, FTG is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 6547340). (*See* Ex. 9.) On information and belief, FTG maintains a registered agent for service of process in Delaware.

12. On information and belief, this Court has personal jurisdiction over FTI. On information and belief, FTI is organized under the laws of the State of Delaware and is registered to conduct business within the State of Delaware (File No. 5638942). (*See* Ex. 10.) On information and belief, FTI maintains a registered agent for service of process in Delaware.

13. On information and belief, this Court has personal jurisdiction over FTH. On information and belief, FTH is organized under the laws of the State of Delaware and is

registered to conduct business within the State of Delaware (File No. 6310412). (*See* Ex. 11.) On information and belief, FTH maintains a registered agent for service of process in Delaware.

14. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c) because Defendants are incorporated in Delaware.

OVERVIEW OF FECAL MICROBIOTA TRANSPLANT THERAPY

15. A typical healthy human gut contains a host of symbiotic microorganisms known as the normal flora (or "microbiota"). The microbiota of a healthy individual is extremely important, as it aids in digestion, stimulates the immune system, modulates energy metabolism, and helps to modulate the growth of opportunistic or "bad" microorganisms. In some situations, the normal microbiota can become disrupted or compromised. For example, use of antibiotics can substantially decrease the gut microbiota, leaving the gut susceptible to rampant overgrowth of pathogenic organisms, including *Clostridium difficile* ("*C. difficile*").

16. *C. difficile* was first isolated in 1935. It was not until 1978, however, that scientists recognized that CDI was associated with human disease and that *C. difficile* was responsible for the majority of cases of antibiotic-associated diarrhea. (Ex. 12 at 1.) *C. difficile* produces two toxins, known as toxin A and toxin B, that cause intestinal inflammation. This inflammation may lead to nausea, diarrhea, colitis, kidney failure, and even death. The incidence of CDI has been increasing over the course of the last twenty years as a result of a more virulent strain of the bacteria that became more prevalent in the early 2000's.

17. In a February 25, 2015 press release, the United States Centers for Disease Control and Prevention ("CDC") released information regarding a 2011 CDC study into CDI in the United States. (Ex. 13 at 1.) According to the study, CDI infects approximately 500,000 people per year and approximately 29,000 people died within thirty (30) days of the initial diagnosis, with about 15,000 of those deaths directly attributable to CDI. (*Id.*) According to the

study, one out of every eleven patients aged sixty-five or older with a healthcare-associated CDI died within thirty (30) days of diagnosis. (*Id.*) With respect to recurrence, the study also found that one out of every five patients with a healthcare-associated CDI had at least one recurrence. (*Id.*)

18. In 2013, the CDC identified *C. difficile* as one of three bacteria that represented an urgent threat that required "urgent public health attention to identify infections and to limit transmission"). (Ex. 14 at 21.) In 2019, the CDC's updated Antibiotic Resistance Threats in the United States continued to list *C. difficile* as an urgent threat, noting that "nearly 223,900 people in the United States required hospital care for *C. difficile* and at least 12,800 people died in 2017." (Ex. 15 at vii, *see also id.* at 3.) The estimated healthcare costs attributable to CDI in the United States in 2017 was approximately $1,000,000,000.00. (*Id.* at 81 of 150.)

19. CDI can be treated by the administration of antibiotics, including metronidazole or vancomycin. In many cases, however, because the normal microbiota is compromised, it is incapable of inhibiting growth of *C. difficile* following the antibiotic regimen. As a result, the *C. difficile* population outcompetes other organisms, resulting in rCDI.

20. Recognizing that disruptions of a normal microbiota impacted the health of individuals, a group of researchers from the Department of Surgery and Medicine, University of Colorado School of Medicine, and the Veterans Administration Hospital, led by Dr. B. Eiseman, attempted to restore the gut microbiota in patients by administering the first fecal transplants in humans recorded in the literature in 1958. (*See* Ex. 16 at 859.) Dr. Eiseman utilized a retention enema composed of "normal feces" from a healthy donor suspended in saline. The recipients of these fecal transplants were observed to experience a "marked improve[ment]", and he recommended that treatment should be further evaluated. (*Id.*)

21. In 1981, Dr. Talmadge Bowden and his team from the Medical College of Georgia and the University of Maryland expanded on the early work of Dr. Eiseman and identified *C. difficile* as the cause of a variety of gastrointestinal problems. (*See, e.g.*, Ex. 17 at 178.) Following the lead of Dr. Eiseman, Dr. Bowden successfully treated the gastrointestinal disorders through restoration of fecal floral homeostasis with "fresh fecal solution" installed through an enema. (*Id*. at 182-83.)

22. Following the successful fecal transplant procedures of Drs. Eiseman and Bowden, researchers began to focus more narrowly on the use of fecal microbiota transplant ("FMT") therapy. For example, in 1998, Dr. Stein Lund-Tonnesen from Stockholm, Sweden successfully applied the methods of Drs. Eiseman and Bowden by treating a significant number of patients suffering from CDI with FMT. As described in an article titled "Clostridium difficile-associated diarrhea treated with homologous feces," Journal of Norwegian Medical Association No. 7, (1998) (Ex. 18 (original Swedish publication) and Ex. 19 (certified English translation)), Dr. Lund-Tonnesen and his team collected fecal samples from pre-screened individuals and diluted the samples with milk. (Ex. 19 at 4, 6.) The slurry was then homogenized and filtered through gauze to ensure easy installation through the narrow biopsy channel of a colonoscope. (*Id.* at 4.) The samples consisted of 20 mL syringes, each containing 5-10 grams of processed feces. (*Id.* at 4.) The syringes with the fecal preparation were frozen at -20 °C and then thawed prior to use. (*Id.* at 4.)

23. In 2009, Dr. Johan Bakken from St. Luke's Hospital, Infectious Disease Associates, in Duluth, Minnesota, added to the growing field of FMT by treating a pool of one hundred patients suffering from rCDI with FMT. Dr. Bakken's work is described in an article titled "Fecal bacteriotherapy for recurrent *Clostridium difficile* infection," Anaerobe 15 (2009)

(Ex. 20). As described in the article, Dr. Bakken collected samples from donors, and pre-screened the samples for contagious agents. (*Id.* at 286-87.) Saline or milk was added as a diluent or diluent/cryoprotectant, respectively, for liquefying the stool samples and protecting the organisms during freezing. (*Id.* at 287.) The samples were subsequently homogenized and filtered through gauze or a coffee filter to remove particulate matter. (*Id.* at 287.) The stool slurry was administered (either fresh or after freezing/thawing) through an enema or by nasogastric or nasojejunal catheter, and successfully treated 89% of the patients that had previously been unresponsive to other forms of rCDI therapy. (*Id.* at 287-88.)

THE DEVELOPMENT OF RBX2660

24. Between 2008 and 2010, Dr. Edwin Hlavka made additional advances in FMT. These advances would become the core technology underlying RBX2660 and are described in U.S. Provisional Applications Nos. 61/337,283 (Ex. 21) and 61/351,184 (Ex. 22), filed February 1, 2010 and June 3, 2010, respectively. A PCT application claiming priority to these applications was filed on February 1, 2011, which published on August 4, 2011 as WO 2011/094027. (Ex. 23.) These applications describe a collection of fresh or frozen fecal samples from pre-screened, healthy donors. (*See, e.g.*, Ex. 21 at 3; Ex. 22 at 25-26; Ex. 23 at 4-6.) The PCT application then states that the samples were then homogenized with a combination of saline and a cryoprotectant (including glycol, glycerol, dimethylsulfoxide, dairy milk, or soy milk) and filtered to remove some of the particulate matter from the samples. (*See, e.g.*, Ex. 23 at 13, 18.) The suspension could then be administered by various methods, including by enema, a gastro-resistant capsule, or with a nasogastric tube. (Ex. 23 at 6.) Dr. Hlavka's application describes further narrowing descriptions of the preexisting FMT technology, including administration of oral capsules, and bacteriotherapy banks. (*See, e.g.*, Ex. 23 at 6, 8, Figure 2.)

25. Rebiotix (formerly MikrobEX, Inc.) was founded in 2011 to further develop the FMT treatments developed by Dr. Hlavka. Rebiotix began developing FMT products to treat patients suffering from certain gastrointestinal disorders, including rCDI.

26. Rebiotix has invested significant time and expense in order to develop RBX2660. For example, Rebiotix began conversations with the FDA in March 2012 regarding the product that would become RBX2660. This included a request for a pre-Investigational New Drug Application ("pre-IND") meeting in October 2012. The FDA granted the pre-IND meeting request and the meeting was held on January 18, 2013.

27. Rebiotix submitted its Investigational New Drug Application ("IND") on March 21, 2013 and the FDA assigned the IND number 15439. As part of its development and communication with the FDA, Rebiotix has responded to various requests for information and provided various complete responses, including information regarding its donor screening procedures and clinical trials.

28. On May 21, 2013, the FDA granted fast track designation status for RBX2660. On March 10, 2014, the FDA granted orphan designation status for RBX2660 for the prevention of recurrent *Clostridium difficile* infection (CDI) in individuals with recurrent *Clostridium difficile* infection. On October 8, 2015, the FDA granted breakthrough therapy designation status for RBX2660.

29. The clinical development program for RBX2660 is the largest ever conducted in the field of microbiome-based therapeutics. For example, Rebiotix has completed five prospective trials with RBX2660. These trials included three Phase 2 studies (PUNCH CD, PUNCH CD2, PUNCH CD Open Label) and two Phase 3 studies (PUNCH CD3 and PUNCH CD2-OLS ad hoc analysis) and represent over a decade's worth of work and development.

30. In a September 29, 2021 press release, Ferring and Rebiotix announced the results of the trials, stating that the trials included 723 actively-treated participants and overall showed that up to 78.9% of the participants remained recurrence-free for eight weeks post treatment (which was defined as treatment success). In those participants who did not respond to initial treatment, an optional additional treatment course was administered, resulting in overall rates of treatment success of up to 84.4%. Notably, most primary responders remained free of CDI for six months and up to two years, with a sustained clinical response success rate of up to 92.1% of the Phase 3 program.

31. In addition to the clinical trials discussed above, Rebiotix previously provided RBX2660 to patients under an FDA enforcement discretion policy allowing for the use of FMT to treat CDI in patients not responding to standard therapies when certain conditions are met. In October 2021, Ferring and Rebiotix, a Ferring Company, presented data from a retrospective analysis at the American College of Gastroenterology 2021 annual scientific meeting. In the analysis, ninety-four (94) participants with comorbid conditions commonly found in people with rCDI were treated with RBX2660. The analysis showed a treatment success rate of 82.8%, with no observable difference between participants who received one dose (83.3%) versus two doses (82.5%).

32. Paul Feuerstadt, MD, FACG, AGAF of the Yale University School of Medicine stated that "[t]he results of this retrospective study provide critical additional information about RBX2660, as it supports the concept that data observed in well-controlled, prospective clinical trials may be replicable in a real-world setting." (Ex. 24 at 2.) Dr. Feuerstadt further explained that "[t]his research shows that even with wide eligibility criteria, RBX2660 performed similarly to the more narrow and limited inclusion for the Phase 2 and 3 trials. This retrospective study

included patients across different comorbidities who are more representative of the population living with *C. difficile* and remain vulnerable to the debilitating cycle of recurrence." (*Id.*)

33. The data from the clinical trials and retrospective analysis of results from use of RBX2660 under the FDA's enforcement discretion policy demonstrate a consistent efficacy and safety profile for RBX2660 that spanned over a decade of work. They reinforce the enormous potential of microbiome-based therapeutics to transform the care of people suffering from rCDI.

34. On information and belief, Defendants were aware of the clinical trials and use of RBX2660 under the FDA's enforcement discretion policy.

THE RELATIONSHIP BETWEEN REBIOTIX AND FERRING

35. Ferring is a research-driven specialty biopharmaceutical company committed to helping people around the world build families and live better lives. Ferring is a leader in reproductive medicine and maternal health and in specialty areas of gastroenterology and urology.

36. Rebiotix was acquired by Ferring Holding Inc. in April 2018. Rebiotix is a late stage clinical microbiome company focused on harnessing the power of the human microbiome to revolutionize the treatment of challenging diseases. With the acquisition of Rebiotix, Ferring is committed to exploring the crucial link between the microbiome and human health, beginning with the treatment of rCDI.

37. Under the terms of the acquisition, Rebiotix was responsible for the IND and remains responsible for the BLA through FDA approval. After approval, ownership of the BLA will be transferred to Ferring, who will be responsible for marketing and selling RBX2660 and Rebiotix will become the manufacturer of the approved product.

REBIOTIX'S BLA NO. 125739

38. On May 3, 2021, Rebiotix initiated the rolling submission process for Biologics License Application ("BLA") No. 125739 ("the BLA") seeking regulatory approval to market and sell RBX2660, packaged as a single dose product in a 250 mL ethylene vinyl acetate bag with a single indication: "to reduce the recurrence of *Clostridium difficile* infection (CDI) in adults following antibiotic treatment for recurrent *Clostridium difficile* infection." The BLA rolling submission was completed on November 30, 2021. As allowed by the fast track and breakthrough therapy designations, Rebiotix requested that the BLA receive accelerated approval and priority review.

39. Upon receiving FDA approval, Ferring intends to launch a commercial version of RBX2660, which will be manufactured by Rebiotix. Plaintiffs expect that RBX2660 will become the first-ever FDA-approved FMT drug for the treatment of rCDI.

40. In addition to the substantial investment in development, clinical trials, and regulatory filings, Ferring has invested substantial resources and effort in understanding the significant unmet medical need for a treatment like RBX2660.

41. For example, Ferring has already invested significant time and resources engaging with advisory boards and key opinion leaders to understand the clinical need for treatment, the current marketing and development landscape, and areas of unmet need. Ferring has also conducted surveys of healthcare providers, talked with national and regional integrated delivery network providers (i.e., integrated healthcare systems), and spent considerable time and effort understanding the market as a whole and how RBX2660 would be positioned in that market.

42. Ferring and Rebiotix have also presented the results of their clinical trials through publications, press releases, and at relevant industry conferences including, for example,

Digestive Disease Week and the American College of Gastroenterology annual scientific meeting.

43. Ferring has also been actively engaged in hiring key management and support personnel, developing education materials, and has dedicated numerous employees to approval and launch activities related to RBX2660.

44. Plaintiffs have made and will continue to make these significant investments in preparation for obtaining expected FDA approval.

DEFENDANTS' ACTIONS SHOW THERE IS A SUBSTANTIAL CASE OR CONTROVERSY

45. As detailed below, Defendants' actions show that there is a substantial case or controversy between the parties and that such case or controversy is real and immediate, such that resolution now is proper.

FTG's S-1 filing

46. On February 26, 2021, FTG submitted an S-1 ("the S-1 filing") with the Securities and Exchange Commission in advance of an anticipated Initial Public Offering. (Ex. 1.) As pled above, on information and belief, defendants FTI and FTH are wholly-owned subsidiaries of FTG.

47. The S-1 filing states that the microbiome therapeutic market is "characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property." (*Id.* at 134.) The S-1 acknowledges the presence of competitors, specifically naming Plaintiff Rebiotix, and notes that "[a]ny advances in microbiome therapies made by a competitor may be used to develop therapies that could compete against our product candidates." (*Id.*)

48. In addition, the S-1 acknowledges the highly competitive marketplace stating:

> Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are safer,

> more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing our product candidates against competitors.

(*Id.*)

49. The S-1 filing further explains that competitive products, such as RBX2660, represent a severe threat should they reach the market first, stating:

> Competing products may gain faster or greater market acceptance than our products, if any, and medical advances or rapid technological development by competitors may result in our product candidates becoming non-competitive or obsolete before we are able to recover our research and development and commercialization expenses. If we or our product candidates do not compete effectively, it may have a material adverse effect on our business, financial condition and results of operations.

(*Id.* at 41.)

50. The S-1 filing states that one of the key advantages of Defendants' platform is the scope and breadth of its patent portfolio. For example, the S-1 filing lists the following as one of the "Key Advantages of Our Platform":

> ***We have built multi-layered patent protection with significant longevity***. We have a large and diverse patent portfolio that embodies pioneering work in the microbiome field. Out patent portfolio consists of over 50 issued U.S. and foreign patents, as well as over 130 patent applications, that have broad relevance for the industry and provide multi-layered protection for our product candidates . . .

(*Id.* at 4 (emphasis in original).)

51. The S-1 filing indicates that Defendants will actively enforce their patent rights to avoid competition. In addition to the above, the S-1 filing also indicates that the management of

Defendants' patent portfolio "leverages both offensive and defensive strategies to protect [their] business," and identifies various tools in their arsenal, including the very patent family at issue here, specifically naming the '107 patent, the '406 patent, and the '413 patent. (*Id.* at 135.) Later, the S-1 filing concludes that "commercial success depends in part on our ability to obtain and maintain proprietary protection," and accordingly, Defendants intend to seek "to prevent others from infringing [their] property rights." (*Id.*)

52. Thus, Defendants have put investors and the world on notice that (1) they have patents directed to FMT products (including the patents in suit), and (2) they intend to enforce them aggressively against competitors, including Plaintiff Rebiotix.

Defendants' patents cover substantially all FMT products, including those products which Defendants are not developing

53. Defendants have attempted to secure broad patent protection for the entire field of FMT, encompassing virtually all FMT technology, including RBX2660. For example, claim 1 of the '406 patent broadly claims "A pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber." (Ex. 6 at cl. 1.)

54. The S-1 filing indicates that Defendants' lead candidate for a commercial product, CP101, consists of a "lyophilized, intact microbial community harvested from rigorously screened healthy donors and formulated in orally administered capsules designed to release at the appropriate location in the gastrointestinal tract." (Ex. 1 at 1.) On information and belief, Defendants have not pursued product formulations other than those for oral administration. On information and belief, Defendants have no intention of developing an enema product.

55. However, Defendants have sought patent protection for claims directed generally to FMT enema products. For example, on information and belief, FTH is the owner by assignment of the '702 and '309 patents, which issued on November 5, 2019 and June 9, 2020,

respectively. These patents generally contain claims directed to enema FMT products, such as Plaintiffs' RBX2660.

56. On information and belief, Defendants sought patents such as the '702 patent and '309 patents based on their knowledge of the RBX2660 clinical trial program and the use of RBX2660 under the FDA's enforcement discretion policy. Both the RBX2660 clinical trial program and RBX2660's use under the FDA's enforcement discretion policy were initiated several years before the applications that would mature into the '702 and '309 patents were filed. (*See* Exs. 3, 4.) On information and belief, Defendants filed these applications as part of their offensive strategy to block Plaintiffs from launching their competitive enema product.

Defendants have challenged Rebiotix's patent in Europe

57. Rebiotix has prosecuted patents to protect its technology world-wide. On November 24, 2017, the European Patent Office ("EPO") issued an Intention to Grant Notice for one such patent, European Patent Number 3,003,330 ("EP 330"). A true and correct copy of the Intention to Grant Notice is attached as Exhibit 25 and a true and correct copy of EP 330 is attached as Exhibit 26.

58. Claim 1 of EP 330 claims:

> A method for manufacturing a microbiota restoration therapy composition, the method comprising:
> collecting a human fecal sample;
> adding a diluent to the human fecal sample to form a diluted sample;
> wherein the diluent includes polyethylene glycol at a concentration of 30-90 g/L;
> mixing the diluted sample with a mixing apparatus;
> filtering the diluted sample;
> wherein filtering forms a filtrate;
> transferring the filtrate to a sample bag; and
> sealing the sample bag.

(Ex. 26 at cl. 1.)

59. On February 8, 2019, European Patent Attorneys at TL Brand & Co., 50 Eastcastle Street, London W1W 8EA, Great Britain, filed an opposition to EP 330 "[i]n the name and on behalf of Strawman Limited of Orchard Lea, Horns Lane, Combe, Witney, Oxfordshire, OX29 8NH." (Ex. 27 at 1.) A true and correct copy of the Opposition is attached as Exhibit 27.

60. According to its website, Strawman Limited indicates that it was created "[t]o relieve you of the time and work in finding a name to front the opposition on behalf of your client." (Ex. 28 at 1.) The "process" section of Strawman Limited's website further states:

> If you wish to oppose a patent and hide behind the name of Strawman Limited ["Strawman™] the process is very simple.
>
> The European Patent Attorney (or any other legal representative entitled to act before the European Patent Office) fills out the online Application Form. The EPA (or any other legal representative entitled to act before the European Patent Office) may be your own selected EPA or may be an EPA selected by another person or organization that acts for you, such as one of your external legal representatives.
>
> That's all there is to it!
>
> There is no requirement to disclose your name and we do not even what to know if you have good cause to file an opposition.

(Ex. 29 at 1.)

61. TL Brand & Co. is also counsel of record at the EPO for at least certain of the European patents that are related to the patents in suit. Both the patents in suit and their European counterparts are owned by one or more of Defendants. For example, TL Brand & Co., 50 Eastcastle Street, London W1W 8EA (GB) is listed as the representative for European Patent Number 3,701,958, which claims priority to the same Australian patent application and the same four United States Provisional Patent Applications (i.e., United States Provisional Application

Number 61/494,363, filed on June 7, 2011, United States Provisional Application Number 61/483,487, filed on May 6, 2011, United States Provisional Application Number 61/451,087, filed on March 9, 2011, and United States Provisional Application Number 61/450,099, filed on March 7, 2011) as the patents in suit. (Ex. 30 at 1.)

62. On information and belief, Defendants or someone acting on behalf of Defendants requested that TL Brand & Co. file an opposition to the EP 330 patent owned by Plaintiff Rebiotix. On information and belief, Defendants or someone acting on behalf of Defendants instructed TL Brand & Co to engage a cover organization (here, Strawman Limited) to serve as the named opponent in the opposition to EP 330 to hide their involvement in the opposition.

63. On information and belief, Defendants, either singly or jointly, control, direct, and are responsible for the opposition to EP 330.

64. Under the totality of facts and circumstances, there is a definite and concrete controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of declaratory judgment relief. Plaintiffs seek a judicial determination that the patents in suit are invalid or not infringed.

THE PATENTS IN SUIT

65. Each of the patents in suit claims foreign application filing priority to Australian Patent Application Number 2010/903,474, filed on August 4, 2010. In addition, each of the patents in suit claim filing priority to United States Provisional Application Number 61/494,363, filed on June 7, 2011, United States Provisional Application Number 61/483,487, filed on May 6, 2011, United States Provisional Application Number 61/451,087, filed on March 9, 2011, and United States Provisional Application Number 61/450,099, filed on March 7, 2011.

66. The ’226 patent was the first in time non-provisional application to be filed in the United States. It was assigned United States Patent Application Number 13/813,915, filed as

PCT/AU2011/000987 on August 4, 2011. Each of the other patents in suit issued from a continuation application that can be traced back to this original filing.

67. On information and belief, the patents in suit each have the same alleged inventor.

The '309 Patent

68. On June 9, 2020, the United States Patent and Trademark Office ("PTO") issued the '309 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them," and names Thomas Borody of Five Dock, Australia as the inventor. A true and correct copy of the '309 patent is attached as Exhibit 2.

69. On information and belief, the '309 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '309 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '702 Patent

70. On November 5, 2019, the PTO issued the '702 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas J. Borody of Five Dock, Australia as the inventor. A true and correct copy of the '702 patent is attached as Exhibit 3.

71. On information and belief, the '702 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '702 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '107 Patent

72. On June 25, 2019, the PTO issued the '107 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and

devices for delivering them," and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '107 patent is attached as Exhibit 4.

73. On information and belief, the '107 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '107 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '899 patent

74. On September 4, 2018, the PTO issued the '899 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '899 patent is attached as Exhibit 5.

75. On information and belief, the '899 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '899 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '406 Patent

76. On July 17, 2018, the PTO issued the '406 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Castle Hill, Australia as the inventor. A true and correct copy of the '406 patent is attached as Exhibit 6.

77. On information and belief, the '406 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '406 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '413 Patent

78. On May 8, 2018, the PTO issued the '413 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and

devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '413 patent is attached as Exhibit 7.

79. On information and belief, the '413 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '413 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

The '226 Patent

80. On April 12, 2016, the PTO issued the '226 patent, which bears the title "Compositions for fecal floral transplantation and methods for making and using them and devices for delivering them" and names Thomas Julius Borody of Five Dock, Australia as the inventor. A true and correct copy of the '226 patent is attached as Exhibit 8.

81. On information and belief, the '226 patent was originally assigned to Crestovo LLC, then Crestovo Holdings LLC, and finally FTH. On information and belief, FTH is now the owner of the '226 patent by assignment recorded at the PTO on December 31, 2020. (Ex. 31.)

COUNT I

Declaratory Judgment of Invalidity of the '309 Patent

82. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

83. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '309 patent.

84. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '309 patent.

85. The ’309 patent has two independent claims. By way of example, independent claim 1 of the ’309 patent claims:

> 1. An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a container, flexible tubing, and a pharmaceutical composition within the container, wherein the pharmaceutical composition is formulated for enema delivery from the container via the flexible tubing, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a preparation of viable uncultured non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the container is sealed, wherein the pharmaceutical composition is free of rough particulate matter, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

(Ex. 2 at cl. 1.)

86. The claims of the ’309 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the ’309 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

87. In addition, the specification of the ’309 patent fails to describe or enable, for example, a composition that is “free of rough particulate matter.”

88. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT II

Declaratory Judgment of Noninfringement of the '309 Patent

89. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

90. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '309 patent.

91. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '309 patent.

92. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '309 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not "free of rough particulate matter" as required by every claim of the '309 patent because a significant amount of particulate matter remains in the suspension when delivered to a patient.

93. Additionally, for at least the reasons described above in Count I, the claims of the '309 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

94. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '309 patent.

COUNT III

Declaratory Judgment of Invalidity of the '702 Patent

95. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

96. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '702 patent.

97. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '702 patent.

98. The '702 patent has two independent claims. By way of example, independent claim 1 of the '702 patent claims:

> 1. An enema product configured for transporting to a remote facility, the enema product comprising a container and a pharmaceutical composition within the container, the pharmaceutical composition formulated for enema delivery directly from the container, wherein the container comprises an oxygen-resistant material, and wherein the pharmaceutical composition comprises saline, a cryoprotectant, and the substantially entire microbiota of a stool sample, wherein the pharmaceutical composition is free of rough particulate matter of the stool sample, wherein the substantially entire microbiota is in an amount effective for treating a *C. difficile* infection.

(Ex. 3 at cl. 1.)

99. The claims of the '702 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '702 patent is anticipated or

obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

100. In addition, the specification of the '702 patent fails to define, describe, or enable, for example, a composition that comprises "the substantially entire microbiota of a stool sample," that is "free of rough particulate matter," or is "in an amount effective for treating *C. difficile* infection."

101. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT IV

Declaratory Judgment of Noninfringement of the '702 Patent

102. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

103. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '702 patent.

104. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '702 patent.

105. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '702 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not "free of rough particulate matter

of the stool sample" as required by every claim of the '702 patent because a significant amount of particulate matter from the stool sample remains in the suspension when delivered to a patient.

106. Additionally, for at least the reasons described above in Count III, the claims of the '702 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

107. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '309 patent.

COUNT V

Declaratory Judgment of Invalidity of the '107 Patent

108. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

109. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '107 patent.

110. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '107 patent.

111. The '107 patent has two independent claims. By way of example, independent claim 1 of the '107 patent states:

> 1. A method comprising: receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device; testing the stool sample for pathogens; mixing the stool sample with a cryoprotectant to form a mixture; and

> homogenizing the mixture to produce a composition comprising viable bacteria from the stool sample.

(Ex. 4 at cl. 1.)

112. The claims of the ’107 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the ’107 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

113. In addition, the specification of the ’107 patent fails to define, describe, or enable, for example, “receiving at a central location a non-frozen stool sample from a donor.”

114. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT VI

Declaratory Judgment of Noninfringement of the ’107 Patent

115. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

116. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the ’107 patent.

117. For example, upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling,

offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '107 patent.

118. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '107 patent, either literally or under the doctrine of equivalents. For example, RBX2660 is not manufactured by "receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device" as required by every claim of the '107 patent.

119. Additionally, for at least the reasons described above in Count V, the claims of the '107 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

120. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '107 patent.

COUNT VII

Declaratory Judgment of Invalidity of the '899 Patent

121. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

122. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '899 patent.

123. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '899 patent.

124. The ’899 patent has two independent claims. By way of example, independent claim 1 of the ’899 patent states:

> 1. A method comprising:
> receiving at a central location a stool sample from a healthy donor;
> placing the stool sample within a stool collection device;
> mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer;
> homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample; and
> selectively removing bacteria from the filtrate to produce a composition comprising bacterial species of the phylum Firmicutes.

(Ex. 5 at cl. 1.)

125. The claims of the ’899 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the ’899 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

126. In addition, the specification of the ’899 patent fails to define, describe, or enable, for example, a filtrate that comprises “a substantially entire microbiota of the stool sample.”

127. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT VIII

Declaratory Judgment of Noninfringement of the ’899 Patent

128. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

129. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the ’899 patent.

130. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’899 patent.

131. Plaintiffs’ manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the ’899 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain a buffer as required by every claim of the ’899 patent.

132. Additionally, for at least the reasons described above in Count VII, the claims of the ’899 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

133. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the ’899 patent.

COUNT IX

Declaratory Judgment of Invalidity of the ’406 Patent

134. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

135. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the ’406 patent.

136. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '406 patent.

137. The '406 patent has two independent claims. By way of example, independent claim 1 of the '406 patent states:

> 1. A pharmaceutical composition comprising an added cryoprotectant and extracted stool bacterial material without fiber.

(Ex. 6 at cl. 1.)

138. The claims of the '406 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '406 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

139. In addition, the specification of the '406 patent fails to define, describe, or enable, for example, a composition that comprises "extracted stool bacterial material without fiber."

140. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT X

Declaratory Judgment of Noninfringement of the '406 Patent

141. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

142. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '406 patent.

143. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '406 patent.

144. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '406 patent, either literally or under the doctrine of equivalents. For example, the RBX 2660 suspension does not contain (i) "extracted stool bacterial material without fiber" and is not (ii) "free of rough particulate matter" as required by every claim of the '406 patent.

145. Additionally, for at least the reasons described above in Count IX, the claims of the '406 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

146. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the '406 patent.

COUNT XI

Declaratory Judgment of Invalidity of the '413 Patent

147. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

148. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the '413 patent.

149. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '413 patent.

150. The '413 patent has two independent claims. By way of example, independent claim 1 of the '413 patent states:

> 1. A method comprising: receiving a stool sample from a healthy donor at a central location, wherein the donor has been prescreened for infectious agents; placing the stool sample within a stool collection device; mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer and a cryoprotectant; homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a substantially entire microbiota of the stool sample.

(Ex. 7 at cl. 1.)

151. The claims of the '413 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the '413 patent is anticipated or

obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

152. In addition, the specification of the '413 patent fails to define, describe, or enable, for example, a filtrate that comprises "a substantially entire microbiota of the stool sample."

153. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT XII

Declaratory Judgment of Noninfringement of the '413 Patent

154. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

155. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the '413 patent.

156. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants' stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the '413 patent.

157. Plaintiffs' manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the '413 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain a buffer as required by every claim of the '413 patent.

158. Additionally, for at least the reasons described above in Count XI, the claims of the ’413 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

159. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the ’413 patent.

COUNT XIII

Declaratory Judgment of Invalidity of the ’226 Patent

160. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

161. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the validity of the ’226 patent.

162. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’226 patent.

163. The ’226 patent has three independent claims. By way of example, independent claim 1 of the ’226 patent states:

> 1. An oxygen-free or substantially oxygen-free pharmaceutical preparation, comprising:
> (a) a formulation comprising:
> (i) a frozen, freeze-dried, spray-dried, lyophilized or powdered entire or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample; or
> (ii) all or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample in an excipient, a saline, a

> buffer, a buffering agent or medium, or a fluid-glucose-cellobiose agar (RGCA) medium,
> (b) an oxygen scavenging material, and
> (c) an air tight or an anaerobic container,
> wherein the pharmaceutical preparation provides an at least about 99.5% oxygen-free or oxygen-free containment or storage of the anaerobic microorganism population of (a)(i) or (a)(ii) in the air tight or the anaerobic container.

(Ex. 8 at cl. 1.)

164. The claims of the ’226 patent are invalid for failure to comply with one or more of the conditions of patentability under Title 35 of the United States Code and related judicial doctrines, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or obviousness-type double patenting. For example, each of the claims of the ’226 patent is anticipated or obvious in light of prior art references including, but not limited to, Lund-Tonnesen, Bakken, and Hlavka, either alone or in combination. (Exs. 18, 19, 20, and 23.)

165. In addition, the specification of the ’226 patent fails to define, describe, or enable, for example, either a composition that comprises “all or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample” or an “entire or at least 90% anaerobic microorganism population of a complete microbiota of a fecal sample.”

166. As a result, there exists a substantial controversy between Plaintiffs and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment of invalidity.

COUNT XIV

Declaratory Judgment of Noninfringement of the ’226 Patent

167. Plaintiffs incorporate by reference and repeat the allegations set forth in the preceding paragraphs.

168. An actual, justiciable, and continuing controversy exists between Plaintiffs and Defendants regarding the infringement of the ’226 patent.

169. Upon obtaining FDA approval, Plaintiffs intend to market RBX2660 in the United States. Due to Defendants’ stated intentions to aggressively enforce their patent portfolio, Plaintiffs reasonably expect that Defendants will assert that the making, using, selling, offering for sale of RBX2660 in the United States, or importation of RBX2660 into the United States infringes the ’226 patent.

170. Plaintiffs’ manufacture, use, sale, offer for sale, or importation of RBX2660 will not infringe, either directly or indirectly, any valid claim of the ’226 patent, either literally or under the doctrine of equivalents. For example, RBX2660 suspension does not contain an oxygen scavenging material as required by every claim of the ’226 patent.

171. Additionally, for at least the reasons described above in Count XIII, the claims of the ’226 patent are invalid. Plaintiffs cannot be held liable for infringement of invalid patent claims.

172. Plaintiffs are therefore entitled to a judicial declaration that their making, using, selling, offering to sell, or importing of RBX2660 has not infringed and will not infringe any valid claim of the ’226 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully requests the following judgment and relief:

a. A declaration under 28 U.S.C. § 2201 that the claims of the patents in suit are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, or obviousness-type double patenting;

b. A declaration that Plaintiffs' RBX2660 does not infringe any claim of the patents in suit;

c. An injunction be issued enjoining Defendants and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Plaintiffs or their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Plaintiffs, or charging them either orally or in writing with infringement of the patents in suit;

d. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Plaintiffs their reasonable attorneys' fees, costs, and expenses; and

e. Any and all other further relief as this Court deems just and proper.

Dated: December 1, 2021

/s/ Mary W. Bourke
Mary W. Bourke (#2356)
Dana K. Severance (#4869)
Daniel M. Attaway (#5130)
John B. ("Ben") Bourke (#6534)
WOMBLE BOND DICKINSON (US) LLP
1313 North Market Street, Suite 1200
Wilmington, DE 19801
Telephone: (302) 252-4320
Mary.Bourke@wbd-us.com
Dana.Severance@wbd-us.com

Daniel.Attaway@wbd-us.com
Ben.Bourke@wbd-us.com